SEP 1 9 2002

K022806

510(k) Summary
for the Modified DuoPro™ Safety Syringe (DuoProSS™)
(per 21CFR807.92)

1. SPONSOR

M.K. Meditech Co., Ltd.
4th Floor, No. 1221
Chung Cheng Road
Taoyuan City
Taiwan 330

Contact Person: I-Ming Shih
Telephone: 886-3-3166399, extension 883
Date Prepared: August 21, 2002

2. DEVICE NAME

Proprietary Name: DuoPro™ Safety Syringe (DuoProSS™)
Common/Usual Name: Hypodermic Syringe (with or without needle)
Classification Name: Piston syringe
Hypodermic single lumen needle

3. PREDICATE DEVICES

- DuoPro™ Safety Syringe (DuoProSS™) (K020623)
- E.N.S.I. Retractable Safety Syringe (K003348, K000572)

4. DEVICE DESCRIPTION

The modified DuoPro™ Safety Syringe (DuoProSS™) is a sterile, single-use, disposable and non-reusable, manual, 3 mL or 5 mL retractable safety syringe, provided with or without needle in various product configurations.

5. INTENDED USE

The modified DuoPro™ Safety Syringe (DuoProSS™) is a sterile, single-use, disposable and non-reusable, manual, retractable safety syringe which is intended for

injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

M.K. Meditech Co., Ltd., makes a claim of substantial equivalence of the DuoProSS™ to the cited predicates based on similarities in intended use, design, and technological and operational characteristics. Both are indicated for injecting fluids into the body, while helping to reduce the risk of sharps injuries. Both syringes are piston syringes that use single lumen hypodermic needles. The DuoProSS™ can be ordered both with and without needles, while the E.N.S.I. is not provided with needles. The modified DuoProSS™ uses either a luer slip or luer lock needle connector, while the E.N.S.I. uses a Luer lock connector. All syringes are provided sterile, single-use, and disposable. The major difference between the modified DuoProSS™ products (3 mL and 5 mL), the original DuoProSS™ (3 mL) and the E.N.S.I. product (5 mL) is the syringe volume (and associated dimensions). This difference does not affect the performance of the syringe, since syringe size is typically determined by drug volume to be administered and user preference. All syringes have two-part plungers. The distal part holds the hypodermic needle and the proximal part has a projection spike that mates with the distal part, thereby locking the needle to the plunger. Both syringes require the user to manually retract the needle-plunger into the syringe barrel, break off the plunger rod, and discard the pieces. M.K. Meditech Co., Ltd., believes that the differences between the modified DuoPro™ Safety Syringe and cited predicate devices are minor and they raise no new issues of safety or effectiveness.

7. TESTING

Verification and validation testing provided in this premarket notification includes standards conformity, testing according to FDA guidance, biocompatibility, and measurement of latex protein. Testing shows that the performance of the modified DuoProSS™ is equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2002

M. K. Meditech Company Limited
C/O Ms. Rosina Robinson
Medical Device Consultants, Inc
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022806
Trade/Device Name: DuoPro™ Safety Syringe (DuoProSS™)
Regulation Number: 880.5860 and 880.5570
Regulation Name: Piston Syringe and Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MEG and FMI
Dated: August 21, 2002
Received: August 23, 2002

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

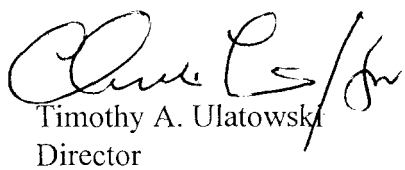
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: M.K. Meditech Co., Ltd., DuoPro™ Safety Syringe (DuoProSS™)

Indications For Use:

The DuoPro™ Safety Syringe (DuoProSS™) is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cuscenta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022806

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)